

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the “United States”), and Patient Services, Inc. (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. When a patient obtains a prescription drug covered by Medicare, the patient may be required to make a payment, which may take the form of a “copayment,” “coinsurance,” or “deductible” (collectively “copays”). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare.

B. Patient Services, Inc. (“PSI”) is a Virginia non-profit corporation with principal executive offices located in Richmond, Virginia. PSI operates disease funds that receive funding from pharmaceutical manufacturers and others, and that then use those payments, less administrative fees that PSI charges, to cover the drug copay obligations of patients, including Medicare patients.

C. PSI has filed a declaratory judgment action that is pending in the United States District Court for the Eastern District of Virginia, captioned *Patient Services, Inc. v. US, et al.*, 3:18-CV16-MHL (hereinafter, “E.D. Va. Litigation”).

D. The United States contends that, between 2010 and 2016, PSI received payments from pharmaceutical manufacturers Insys Therapeutics, Inc. (“Insys”), which sold Subsys, Aegerion Pharmaceuticals, Inc. (“Aegerion”), which sells Juxtapid, and Alexion

Pharmaceuticals, Inc. (“Alexion”), which sells Soliris, and then caused claims for payment for Subsys, Juxtapid, and Soliris to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”).

E. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against PSI for engaging in the conduct below during the period from 2010 through 2016 (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges that PSI, under the direction and/or control of its former leadership, permitted Insys, Aegerion, and Alexion to use PSI as a conduit to pay kickbacks, in the form of reimbursement for copays to Medicare patients taking certain of their drugs, as follows:

PSI’s Breakthrough Cancer Pain Fund. In late 2013, PSI and Insys began discussing a potential copayment assistance fund for Subsys, a sublingual form of fentanyl, a powerful opioid painkiller. Subsys was approved for the treatment of breakthrough cancer pain in opioid-tolerant patients. PSI worked with Insys to create a budget for the “Breakthrough Cancer Pain” fund. Insys was the only donor to the fund. PSI provided Insys, through the Insys Reimbursement Center, with access to a “referral portal,” where Insys could see the status of each patient that it referred to PSI, including whether that patient had received copay assistance from PSI and the amount of the assistance. PSI did not provide access to the referral portal to other manufacturers of fentanyl products that did not donate to the fund. PSI knew that Insys was referring patients to the Breakthrough Cancer Pain fund who did not have cancer, but PSI stated that it would only prevent “off-label use...if the Donor wants us to.” PSI provided Insys with monthly “invoices” to cover the patients who had received assistance from PSI. PSI worked to avoid covering patients taking fentanyl products other than Subsys, noting that PSI “cannot allow them to deplete funds from INSYS.”

PSI's HoFH Fund. Aegerion sold Juxtapid, which is approved to treat patients with homozygous familial hypercholesterolemia ("HoFH"). In 2013, at Aegerion's request, PSI created a fund, supported only by Aegerion donations, for HoFH. PSI represented to Aegerion that "it makes more sense to have industry provide a very small amount of funding [in the form of donations for copayment coverage] to gain a reimbursement vehicle rather than give compassionate product." PSI's HoFH fund allowed Aegerion to pay for Medicare patients' copayments to eliminate any price sensitivity to physicians prescribing and patients taking Juxtapid. Aegerion participated in establishing the patient eligibility criteria that PSI used to cover the copayment obligations of patients taking Juxtapid.

PSI's CMD Fund. Alexion sells Soliris, an intravenously administered complement inhibitor. From January 1, 2010, through June 30, 2016, Soliris was indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria ("PNH") to reduce hemolysis and for the treatment of patients with atypical hemolytic uremic syndrome ("aHUS") to inhibit complement-mediated thrombotic microangiopathy. Alexion approached PSI in January 2010 to request that PSI create a fund to provide Soliris patients with financial assistance, such as coverage for Medicare copays for Soliris, health insurance premiums, infusion and nursing services, and travel expenses. Over the next several months, Alexion and PSI discussed the coverage parameters that Alexion desired for the fund, including Alexion's desire that PSI "not support a patient with any of these diagnoses for other reasons tha[n] Soliris therapy." PSI opened an orphan disease fund entitled Complement Mediated Diseases ("CMD") to provide assistance to patients taking Soliris. Except in rare instances, PSI provided financial assistance from the CMD fund only if a patient was taking Soliris. PSI provided Alexion with access to PSI's referral portal software, through which PSI reported information back to Alexion confirming the specific

Soliris patients who were approved for copay or other financial assistance from PSI and through which PSI detailed payments to those patients.

As a result of the foregoing conduct, the United States contends that PSI caused false claims for Subsys, Juxtapid, and Soliris to be submitted to Medicare.

F. In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. PSI shall pay to the United States three million dollars (\$3,000,000) (the “Settlement Amount”) no later than ten days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for District of Massachusetts.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon PSI’s full payment of the Settlement Amount, the United States releases PSI, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of PSI in this Agreement and the Integrity Agreement (“IA”) entered into between OIG-HHS and PSI, and conditioned upon PSI’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against PSI under

42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude PSI from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in Paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and

- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. Within seven (7) days of making the payments described in Paragraph 1, above, PSI shall file a stipulation of dismissal with prejudice in the E.D. Va. Litigation.

6. In the event that the E.D. Va. Litigation is not dismissed with prejudice pursuant to Paragraph 5, above, this Agreement may be rescinded by the United States. If the United States opts to rescind this Agreement, PSI agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to PSI that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent that these defenses were available on the Effective Date of this Agreement.

7. PSI has provided sworn financial disclosure statements and follow up information (“Financial Statements”) to the United States, and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. PSI warrants that the Financial Statements are complete, accurate, and current as of the Effective Date of the Agreement. If the United States learns of asset(s) in which PSI had an interest at the time of this Agreement that were not disclosed in the Financial Statements, other than donations subsequently received or investment income earned in the ordinary course of PSI’s operations or if the United States learns of any misrepresentation by PSI on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$250,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the

Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of PSI previously undisclosed. PSI agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

8. In the event that the United States, pursuant to Paragraph 7 (concerning disclosure of assets), above, opts to rescind this Agreement, PSI agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to PSI that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

9. PSI waives and shall not assert any defenses PSI may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

10. PSI fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that PSI has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and PSI agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

12. PSI agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of PSI, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s), and any civil or criminal investigations of the matters covered by this Agreement;
- (3) PSI's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and any civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment PSI makes to the United States pursuant to this Agreement; and

(6) the negotiation of, and obligations undertaken pursuant to the IA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the IA; and (ii) prepare and submit reports to the OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (“FEHBP”) (hereinafter referred to as “Unallowable Costs”). However, nothing in paragraph 12.a.(6) that may apply to the obligations undertaken pursuant to the IA affects the status of costs that are not allowable based on any other authority applicable to PSI.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by PSI, and PSI shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by PSI or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: PSI further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by PSI or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment

requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. PSI agrees that the United States, at a minimum, shall be entitled to recoup from PSI any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by PSI or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on PSI or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine PSI's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 14 (waiver for beneficiaries paragraph), below.

14. PSI agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

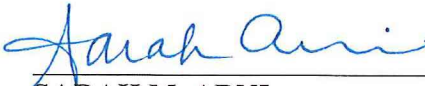
21. This Agreement is binding on PSI's successors, transferees, heirs, and assigns.

22. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


23. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 1/17/20

BY: 
SARAH M. ARNI
AUGUSTINE M. RIPA
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1/21/20 BY:


GREGG SHAPIRO
ABRAHAM GEORGE
Assistant United States Attorneys
United States Attorney's Office
the District of Massachusetts

DATED: _____

BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

SARAH M. ARNI
AUGUSTINE M. RIPA
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

GREGG SHAPIRO
ABRAHAM GEORGE
Assistant United States Attorneys
United States Attorney's Office
the District of Massachusetts

DATED: 01/17/2020

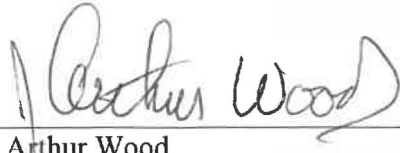
BY: _____

Lisa M. Re
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

PATIENT SERVICES, INC.


DATED: 1/17/2020

BY:


J. Arthur Wood
Chief Executive Officer
Patient Services, Inc.

DATED: 1/17/2020

BY:


William A. Sarraille
Jack W. Pirozzolo
Robert D. Keeling
Sidley Austin LLP
Counsel for Patient Services, Inc.